510(k) SUMMARY
(Per 21CFR807.92)

510(k) Owner:

Owner/Operator:
W. L. Gore & Associates, Inc.
1505 N. Fourth Street
Flagstaff, AZ 86004

SEP 0 6 2013

Regulatory Contact:
W. L. Gore & Associates, Inc.
301 Airport Road
Elkton, Maryland 21921
Barbara L. Smith
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E-mail: blsmith@wlgore.com

Date Prepared:
May 15, 2013

Device Names/Classification

Trade Name:	GORE® SEAMGUARD® Reinforcement
Common Name:	Staple line reinforcement material
Classification Name:	Mesh, Surgical, absorbable, staple line reinforcement (21CFR878.3300)
Product Code:	OXC

Predicate Device

- K043056 GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement Material

Device Description

The subject GORE® SEAMGUARD® Reinforcement device is an assembly of three components: 1) the implantable device, 2) two (2) loading carriers (for anvil & cartridge side of stapling device), and 3) a protective cover. The implantable

device consists of three layers – Web, Film, and Adhesive. The Web and Film layers are comprised of synthetic bioabsorbable polyglycolide (PGA) and trimethylene carbonate (TMC). A thin layer of bioabsorbable adhesive is coated onto one surface of the implantable device, and is composed of a synthetic bioabsorbable polylactide and trimethylene copolymer. The adhesive's function is to affix the device onto the surgical stapler for delivery to the implant site. The bioabsorbable copolymers degrade via a combination of hydrolytic and enzymatic pathways. The device is supplied sterile for single use only.

Indications for Use

GORE® SEAMGUARD® Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Reinforcement can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures. GORE® SEAMGUARD® Reinforcement is also intended to be used for reinforcement of staple lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Summary of Similarities and Difference in Technological Characteristics, Performance and Intended Use

The intended/indications for use for the subject SEAMGUARD device is identical to the predicate SEAMGUARD device. The primary difference between the subject and predicate SEAMGUARD devices is in the feature for loading and delivery of the device to the implantation site. The subject SEAMGUARD device utilizes loading carriers and an adhesive to secure the device on the stapler as an alternative to the sleeve with suture pull cord feature of the predicate SEAMGUARD device.

Performance Data / Predicate Device Comparison

Non-Clinical

Bench study: Testing of the GORE® SEAMGUARD® Reinforcement consisted of a simulated use performance testing. The tests demonstrated the performance of the subject SEAMGUARD device is substantially equivalent to the predicate SEAMGUARD device.

Animal study: Testing of the GORE® SEAMGUARD® Reinforcement device also included biocompatibility testing in accordance with ISO

10993-1 and in vivo safety studies. The results of these tests revealed the device is biocompatible for its intended use and demonstrated no clinically relevant device-related complications, no adverse tissue response, and histological results comparable to the predicate device.

Clinical: No clinical evaluations of this product have been conducted.

Conclusion

W.L. Gore & Associates concludes that the subject GORE® SEAMGUARD® Reinforcement device is *substantially equivalent* to the predicate GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement device in terms of indications for use, design, materials, biocompatibility, packaging, sterilization, labeling, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

W.L. Gore & Associates, Incorporated
% Ms. Barbara L. Smith
301 Airport Road
Elkton, Maryland 21921

September 6, 2013

Re: K131658
Trade/Device Name: GORE® SEAMGUARD® Reinforcement
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: OXC
Dated: August 9, 2013
Received: August 20, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131658

Device Name: GORE® SEAMGUARD® Reinforcement

Indications For Use:

GORE® SEAMGUARD® Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Reinforcement can be used for reinforcement of staple lines during hysterectomy, lung resection, liver resection, bladder reconstruction, bronchial, bariatric, colon, colorectal, esophagus, gastric, mesentery, pancreas, small bowel, and spleen procedures. GORE® SEAMGUARD® Reinforcement is also intended to be used for reinforcement of staple lines (i.e., occlusion of the left atrial appendage during open chest procedures) during cardiac surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause -S

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131658